

Notice of Allowability

Application No.

10/726,467

Examiner

Charleswort Rae

Applicant(s)

LI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 8/6/07 and Telephonic Interview on 10/24/07.
2. ☒ The allowed claim(s) is/are 10-17, 22-31 and 38.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 10/25/07.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

BRIAN-YONG S. KWON
PRIMARY EXAMINER



EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Matthew Pavao on October 25, 2007.

The application has been amended as follows:

In claims 10, 11, 13, 14, 15, 16, and 17 in page 1, delete [or a derivative or analog thereof] after " β -lapachone".

In claims 23, 24, 25, 26, 27, and 28 in page 2, delete [or a derivative or analog thereof] after " β -lapachone".

In claims 29, and 38 in page 3, delete [or a derivative or analog thereof] after " β -lapachone".

In claim 30, line 4 in page 3, delete [or analogs thereof] after "alpha-cyclodextrin".

In claim 30, line 4 in page 3, delete [or analogs] after "beta-cyclodextrin".

In claim 30, line 5 in page 3, delete [thereof] before ", gamma-cylcodextrin".

In claim 30, line 5 in page 3, delete [or analogs thereof] after "gamma-cylcodextrin".

In claim 38, line 1 in page 3, delete [or chronic myelogenous leukemia] after "myeloma".

In claim 38, line 3 in page 3, delete [or] after "myeloma".

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In claim 38, line 4 in page 3, delete [chronic myelogenous leukemia] before "is".

Claims 1-9, 18-21, 32-37, and 39 are cancelled.

Reason for Allowance

2. Applicant's showing of unexpected results of synergistic effect as provided by Example 1, including Table 3 (specification pages 28-29).

The rejection under 112, second paragraph (claims 4, 6, and 7) is withdrawn in view of the claim amendment canceling said claims.

The scope of enablement rejection under 112, first paragraph, is withdrawn as applicant's arguments and amendment are found to overcome the instant rejection.

The written description rejection under 112, first paragraph, is withdrawn in view of the amendment narrowing the scope of the claims to a method of treating multiple myeloma comprising β -lapachone and imatinib.

The rejection under 103(a) is withdrawn in view of applicant's showing of unexpected synergistic effects (specification pages 28-29, Example 1 and Table 3).

The Nonstatutory Obviousness-Type Double Patenting (ODP) rejections are withdrawn in view of the following:

a) The ODP rejection based on Pardee '797, Topay et al., and Pardee '288 is withdrawn in view of the difference in the scope of the instant invention as compared with the cited references as evidenced by the fact that Pardee '797 is directed to a combination of β -lapachone and paclitaxel.

b) The ODP rejection based on Pardee '288, Pardee '797, Topay et al., and Lyons is withdrawn in view of the difference in the scope of the instant invention as

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compared with the cited references as evidenced by the fact that Pardee '288 does not teach the instant claimed combination.

c) The Provisional ODP rejection based on copending application No.

10,007,352, now abandoned.

d) The Provisional ODP rejection based on copending application No.

10/846,980 is withdrawn pursuant to MPEP 1504.06:

If a provisional double patenting rejection (of any type) is the only rejection remaining in two conflicting applications, the examiner should withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the provisional double patenting rejection in the other application which rejection will be converted into a double patenting rejection when the first application issues as a patent. If more than two applications conflict with each other and one is allowed, the remaining applications should be cross rejected against the others as well as the allowed application. For this type of rejection to be appropriate, there must be either at least one inventor in common, or a common assignee. If the claims in copending design applications or a design patent and design applications have a common assignee but different inventive entities, rejections under 35 U.S.C. 102(c), (f) and (g)/103(a) must be considered in addition to the double patenting rejection. See MPEP Section 804, Section 2136, Section 2137 and Section 2138.

Conclusion

3. Claims 10-17, 22-31, and 38 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

25 October 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'B-Y Kwon', followed by a long horizontal line extending to the right.